

### **REMARKS**

Applicants respectfully request reconsideration of the claims of this application in light of the present amendment. Claims 27-36 have been added.

The specification has been amended to remove a dangling participle on page 7, line 30. The specification has also been amended to remove a duplicate "in" on page 10, line 27, and to correct the last sentence of the paragraph spanning pages 10 and 11.

Each of the independent claims (i.e., claims 1, 11, 16, and 23) have been amended to include a limitation requiring the iron-fortified beverage to remain essentially free of iron-related organoleptic defects for specific time periods under ambient or regular storage conditions; newly added independent claims 27 and 33 also have such a limitation. Thus, each of the pending claims now contain such a limitation. Support for this amendment can be found in the specification in Examples 1 and 3 and Figure 1.

The time duration for stability in independent claims 1, 11, and 23, all of which are directed to **beverages** prepared using ferric EDTA, is at least three months. Example 2, which is directed to inventive beverages, shows that inventive beverages remain essentially free of iron-related organoleptic defects under accelerated storage conditions for at least three weeks (equivalent to at least three months under regular or ambient storage conditions).

The time duration for stability in independent claims 16, 27, and 33, which are directed to the **powdered mixture** containing ferric EDTA (or use thereof), is at least twelve months. Example 1, which is directed to inventive powdered mixtures, shows that the powdered inventive powdered mixture was stable for more than about 16 weeks under accelerated shelf life conditions (thus, under normal or ambient storage conditions, shelf life would be at least 12 months and even longer); the results of Example 1 are presented graphically in the Figure for sixteen weeks of storage. This Figure clearly shows that the inventive powdered mixture remains stable for at least about 10 weeks accelerated shelf life conditions (and longer); since each week of accelerated storage is equivalent to about 1.25 to 1.5 months of

ambient storage (see Example 1), the powdered mixture is stable for at least 12 months. As also shown in Example 1, the powdered mixture samples were stored for the desired time period; organoleptic evaluation was carried out by withdrawing a sample of the powdered mixture, reconstituting in the potable liquid, and then evaluating the organoleptic properties of the resulting beverage within a short time period.

Claim 1 has also been amended to supply a missing "an" before the word "amount" in line 2. Claim 4 has been amended to add the missing word "percent" as requested by the Examiner. Claim 12 has been amended to supply a missing "an" before the word "amount" in line 2. Claim 19 has been amended to replace the first word "A" with the word "The" at the beginning of the claim. Claim 22 has been amended to replace the word "comprising" with the word "comprises". Claim 23 has also been amended to supply a missing "an" before the word "amount" in line 4.

Claims 27-32 have been added. These claims are essentially the same as claims 16, and 18-22, except that the limitation requiring a stabilizer has been removed. As indicated on page 9, lines 3-11, the stabilizer is an optional ingredient mainly used in nonfat beverage products. Additionally, the inventive ready-to-drink (RTD) beverage of Example 3 does not include such a stabilizer.

Claims 33-36 also have been added. These claims are essentially the same as claims 23-26, except that the iron-fortified beverage is specifically prepared by mixing a soluble powdered beverage mixture comprising ferric EDTA with a potable liquid in amount effective to dissolve at least substantially all of the ferric EDTA.

No new matter has been added in this amendment.

#### Objection to Claim 4

The Examiner objected to claim 4 since the word "percent" was missing on line 2. The claim has been corrected. Applicants respectfully request that this rejection be withdrawn.

#### Rejection Under 35 U.S.C. §103

Claims 1-26 have been rejected under 35 U.S.C. §103 as being obvious over

Viteri et al. (Am. J. Nutr. 61: 1153-63 (1995) in view of Humbert et al. (U.S. Patent 5,667,825) and Henry et al. (U.S. Patent 6,509,045). According to the Examiner,

“Viteri et al. disclose a beverage composition of fruit juice (potable liquid), coffee and tea, containing sugar fortified with ferric EDTA (FE) (page 1154, col. 1, last para. and col. 2 1<sup>st</sup> par.). Juices are seen to contain[] natural flavorings as are coffee and tea. Humbert discloses as prior art in col. 2, that it is known to use FE in a fish sauce (col. 2, lines 12-22). Certainly, a fish sauce is flavored with the flavor of fish. Henry et al. '045 disclose a beverage composition that contains ferric ions and EDTA as a complexing agent to prevent off-colors caused by fortification with iron (abstract and col. 4, lines 14-20, col. 10, lines 44-65 and col. 11, lines 1 and 2). Nothing is seen that ferric iron is not chelated with EDTA to make ferric EDTA. Claims 1 and 2 differ from the reference in the use of an amount of liquid effective to dissolve the FE. However, no problems were mentioned as to the FE not being dissolved in the beverages (page 1156, col. 2). Certainly, it is known that sugar dissolves well in water.<sup>1</sup> Therefore, it would have been obvious to make a composition as shown by Viteri et al. containing the claimed composition as shown by the reference to Viteri et al.”<sup>2</sup> (Footnotes added.)

Applicants respectfully disagree. The three references cited by the Examiner, alone or in combination, do not render the present invention obvious.

Viteri et al. discloses the **use of vitamin A-fortified sugar** which was then further fortified with small amounts of ferric EDTA. As noted on page 1154 (col. 1), the ferric EDTA was added to vitamin A-fortified sugar before the final drying step (i.e., in the last centrifugation step in which the sugar still contained about 2 percent humidity) and then dried. Viteri et al. does disclose the use of such sugar fortified with vitamin A and ferric EDTA in various cookies, cakes, sweet bread preparations, chuchitos, fruit-based and corn starch-based deserts as wells as fruit drinks, coffee and tea. Page 1154, ¶ spanning cols. 1 and 2. Although not mentioned by the

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<sup>1/</sup> Applicants do not understand the significance of the water solubility of sugar relative to the water solubility of materials which may be added to the sugar (e.g., ferric EDTA in Viteri et al.). Clearly, mere fortification of sugar with an insoluble substance does not change the solubility of the sugar (still soluble) or the insoluble substance (still insoluble).

<sup>2/</sup> Applicants also do not understand the last sentence of this paragraph wherein the Examiner appears to be saying that the present invention is obvious “over Viteri et al. in view of Viteri et al.” Based on the complete paragraph, Applicants assume the Examiner wished to include the other two cited references as the secondary references to be combined with Viteri et al.

Examiner, Viteri et al. does include some stability data. That stability data is only related to stability of the sugar itself which has been fortified with ferric EDTA and vitamin A. There is apparently **no data in this reference on the food products or beverages in which the sugar is added**. Moreover, even the stability data on the fortified solid sugar was apparently limited to observation of “[n]o settling of FeNaEDTA or vitamin A to the bottom of sacks stored under ‘natural’ storage conditions” in Guatemala and an indication of “a very slow progression of brownish discoloration” of the solid fortified sugar over long storage times. Page 1156, 2<sup>nd</sup> col.

Humbert et al. is directed to ready-to-eat cereal products fortified with ferric EDTA as an iron source. Humbert et al. also indicates that other solid foods (i.e., waffles, snack bars, toaster pastries, and pastry products) can be fortified with ferric EDTA. Col. 8, lines 31-34. Humbert et al. does not mention any use of ferric EDTA in a beverage. In fact, Humbert et al. effectively teaches away from the use of ferric EDTA in a beverage type product by noting that “often the ready-to-eat cereal is mixed with milk or other liquid, which can destabilize the cereal piece containing the iron fortificant including ferric EDTA.” Col. 8, lines 7-15. Humbert et al. does allege that the prior art teaches the use of ferric EDTA in food ingredients or condiments (such as fish sauce, curry powder, or flat breads).<sup>3</sup> Col. 2, lines 12-22. Of course, none of these alleged prior art uses include beverages.

Henry et al. is directed to color stable iron and zinc fortified compositions (including beverages and dry mixes) for preparing beverages. Henry et al. notes that color develops in iron fortified beverages “when ferrous ion is converted to ferric ion that then complexes with other dietary components.” Col. 4, lines 14-17. Henry et al. then indicates that:

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<sup>3</sup> The Examiner apparently relies on Humbert et al. only to “show” that the prior art teaches the use of ferric EDTA in condiments such as fish sauce which “is flavored with the flavor of fish.” Although Applicants believe that the present invention is not obvious over the references cited, alone or in combination, Applicants respectfully submit that this use of Humbert et al. in this manner is improper. Humbert et al., in relevant portion, states that “[o]ther known uses of ferric EDTA, under experimental conditions, are found in food ingredients or condiments, i.e., fish sauce in Thailand (Garby et al., 1974, Ann. Tro. Med. Parasitol. 68: 467-76) . . . .” Rather than relying on Humbert et al. for the use of ferric EDTA in fish sauce, the Examiner should rely on the primary reference Garby et al. and supply Applicants with a copy. Only in this manner would Applicants be able to evaluate this alleged use of ferric EDTA in light of the complete Garby et al. reference.

“it has been surprisingly found that ferric iron will not cause such off-color if a ferric iron reducing agent, such as ascorbic acid, and/or an agent such as citric acid that is capable of preferentially complexing with ferric iron in the presence of polyphenols or flavonoids that are typically present in these beverages or foods, is included in appropriate amounts. The ability of these complexing agents and/or reducing agents to prevent off-color development has also found to be pH dependent.” Col. 4, lines 19-26.

One of ordinary skill in the art would understand that Henry et al. is **NOT directed to use of ferric EDTA**. Henry et al. merely uses ferric ion reducing agents or ferric ion complexing agents (including EDTA as mentioned at col. 10, lines 63-65) to effectively remove or tie up any ferric ion that may be converted from the ferrous iron used to fortify the beverage. Col. 11, lines 3-6. The amount of such ferric ion that may be produced, and thus needs to be tied up, should be relatively small. Thus, Henry et al. does not teach or suggest that ferric EDTA itself should be used as an additive; rather EDTA can be added such that, if any free ferric ion is produced, it is tied up. Moreover, Henry et al. does not teach or suggest that any ferric iron which is tied up with EDTA would act as a source of dietary iron. In contrast, Henry et al. does teach that certain ferric salts (but not ferric EDTA) can be used as an additive; these include “ferric saccharate, ferric ammonium citrate, ferric citrate, ferric sulfate, ferric chloride, as well as mixtures of these ferric salts.” Col. 6, lines 5-10. Notably, ferric EDTA is not in this list of suitable ferric salts for use as a source of iron in beverages.

As noted above, all pending claims contain a limitation regarding the stability of the powdered mix or the RTD beverages of this invention. As noted in the specification, the absence of iron-related organoleptic defects appears to be due to fact that little or no free iron is available to produce off-flavors or off-colors. More specifically, it is noted in the specification that

“iron in the ferric EDTA does not appreciably interchange with other cations often present in a beverage formulation with added vitamin/mineral mixes (e.g., sodium, calcium, potassium, zinc, iodine, vitamin C, vitamin E, and the like). As a consequence, no significant free iron is generated in solution to be available to react and form off-flavors or colors, as is often the case for other soluble iron forms.” Page 4, lines 8-14.

and

"The form of iron used in the present invention (i.e., ferric EDTA or sodium iron EDTA) is water soluble and thus ostensibly would be expected to have high reactivity in high moisture and aqueous food/beverage products and be prone to developing off-flavors and off-colors. In other words, with the extremely high water content and activity in beverages, one would normally expect the iron ions in the ferric EDTA to be interchangeable with other cations commonly present in beverages (e.g., sodium or calcium), thereby allowing free iron ions to be available to react and form off-flavors or off-colors (as is often the case for soluble iron forms). Surprisingly, this has not been found to occur in using ferric EDTA to fortify beverages according to this invention.

"As illustrated in the examples described below, it has been demonstrated that ferric EDTA does not develop undesirable metallic off-flavors or off-colors in either reconstituted powdered beverages or in ready-to-drink beverages. Moreover, acceptable taste results were achieved in beverages fortified with ferric EDTA according to this invention, at levels exceeding comparative beverages that were fortified with other iron forms. Namely, iron- related organoleptic defects in terms of metallic off-tastes, flavor oxidation, and/or stale-taste attributes normally associated with iron fortificants have not been detected by evaluators sampling beverages fortified with ferric EDTA according to this invention." Page 5, line 29, through page 6, line 20.

None of the references cited by the Examiner teach such stability. Viteri et al., for example, provides stability data which is only related to stability of the sugar itself which has been fortified with ferric EDTA and vitamin A. There is apparently **no data in this reference on the food products or beverages in which the sugar is added**. Moreover, even the stability data on the fortified solid sugar in Viteri et al. was apparently limited to observation of "[n]o settling of FeNaEDTA or vitamin A to the bottom of sacks stored under 'natural' storage conditions" in Guatemala and an indication of "a very slow progression of brownish discoloration" of the solid fortified sugar over long storage times. Page 1156, 2<sup>nd</sup> col.

As noted above, Humbert et al. does not mention any use of ferric EDTA in a beverage. In fact, Humbert et al. effectively teaches away from the use of ferric EDTA in a beverage type product by noting that "often the ready-to-eat cereal is mixed with milk or other liquid, which can destabilize the cereal piece containing the iron fortificant including ferric EDTA." Col. 8, lines 7-15.

As noted above, Henry et al. merely uses ferric ion reducing agents or ferric

ion complexing agents (including EDTA as mentioned at col. 10, lines 63-65) to effectively remove or tie up any ferric iron that may be converted from the ferrous iron used to fortify the beverage. Col. 11, lines 3-6. Henry et al. does not use ferric EDTA as a fortification agent; thus, Henry does not provide any guidance as the stability of ferric EDTA in beverages.

The references cited by the Examiner cannot render the present invention obvious. As indicated above, at least some of the cited references teach away from the present invention. Applicants respectfully request that this rejection be withdrawn.

As for newly added claims 27-32, Applicants note that these claims are the same as amended independent claims 16 and dependent claims 18-26 except that the stabilizer is no longer required. As for newly added claims 33-36, Applicants note that these claims are essentially the same as amended claims 23-26 except that the iron-fortified beverage is specifically prepared by mixing a soluble powdered beverage mixture comprising ferric EDTA with a potable liquid. These newly added claims are allowable for the same reasons as presented above.

As noted above, each of the original independent claims has been amended to include, and newly added independent claims 27 and 33 include, a limitation regarding stability of the beverage mix or beverage. Based on the arguments presented above and the fact that all dependent claims also contain this limitation, Applicants believe that all claims are allowable. Applicants respectfully submit that the Examiner's rejections or objections on pages 2-6 of the Office Action with regard to specific limitations in the dependent claims have been rendered moot by the present amendment. Thus, it is not necessary to consider these additional rejections or objections. Applicants do not, however, necessarily agree with those rejections or objections and merely indicate that it is not necessary to respond to them at this time in light of the amendments made to the claims in the present response. Applicants reserve the right to respond to these rejections or objections if presented in any later office action that may be issued by the Examiner using the presently cited references and/or newly cited references.

**CONCLUSION**

Applicants respectfully submit that all pending claims 1-36, as amended, are in condition for allowance and respectfully request that this case be passed to issuance.

The Commissioner is hereby authorized to charge any additional fees which may be required in the Application to Deposit Account No. 06-1135.

Respectfully submitted,

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